AHWP TC WG2
Survey on Post Market Surveillance & Vigilance System

Name: _____

Email Address: _____

Organization: _____

Country/Economy: _____

Section one: Organization and infrastructure

1. Has your country/economy established any medical device regulatory system?

   ☐ Yes ☐ No

   (a) If yes, is it mandatory or voluntary?

   ☐ Mandatory ☐ Voluntary

   (b) Is it under medical device or pharmaceutical law?

   ☐ Medical Device ☐ Pharmaceutical

2. Has your country/economy established any post market surveillance and vigilance system for medical devices?

   ☐ Yes ☐ No (**if no, please jump to Section five)**

   (a) If yes, is it mandatory or voluntary?

   ☐ Mandatory ☐ Voluntary

3. Who in your organization (name, email and contact address for contact purpose) is in charge of the post market surveillance and Vigilance activities?

   Name: _____

   Email: _____

   Contact Address: _____

4. How many people are there in your post-market surveillance and vigilance team?

   ☐ 1 – 5 people ☐ 6 – 10 people ☐ More than 10 people

Section two: Scope & Requirements

1. Scope of Post-Market Surveillance and Vigilance System (You can choose more than one)

   ☐ Recalls ☐ Safety alerts ☐ adverse event reporting ☐ Sample test
   ☐ Others (please specify):

   _____
   _____

2. Regular post-market surveillance and vigilance activities carried out by regulatory authority

   _____
   _____

3. Regular post-market surveillance and vigilance activities carried out by manufacturers or their representatives

   _____
   _____

4. Regular post-market surveillance and vigilance activities carried out by traders

   _____
   _____

5. Regular post-market surveillance and vigilance activities carried out by users

   _____
   _____

6. Who is required to report adverse events? (You can choose more than one)

   ☐ Manufacturers ☐ Importers ☐ Distributors

   ☐ User facilities ☐ Users ☐ CAB (Conformity Assessment body)

7. What is the timeline for reporting adverse events? (You can choose more than one)

   ☐ Death Reporting timeline:_____

   ☐ Happen in your jurisdiction only

   ☐ Happen inside and outside your jurisdiction

- ☐ Serious injury: Reporting timeline:_____
  - ☐ Happen in your jurisdiction only
  - ☐ Happen inside and outside your jurisdiction
- ☐ Near incident Reporting timeline:_____
  - ☐ Happen in your jurisdiction only
  - ☐ Happen inside and outside your jurisdiction
- ☐ Device malfunction Reporting timeline:_____
  - ☐ Happen in your jurisdiction only
  - ☐ Happen inside and outside your jurisdiction

8. What are the means of reporting?
   - ☐ Email, Please specify email address_____
   - ☐ Specific form, Please specify the form location_____
   - ☐ Website, Please specify reporting website_____

Section three: Withdrawal and Recall

1. What is the definition of recall?

   _____
   _____

2. Do you require Manufacturers/representatives to report recalls/corrective actions?
   - ☐ Yes
     - ☐ Happen in your jurisdiction only
     - ☐ Happen inside and outside your jurisdiction
   - ☐ No

3. What is your country/economy recall notification procedure?

   ☐ Email. Please specify email address_____

   ☐ Specific form. Please specify the form location_____

   ☐ Website. Please specify reporting website_____

Section four: Additional information

1. If you have any thematic website for the regulation of medical devices, please specify.

   _____

   _____

2. If the AHWP Safety Alert Dissemination System (SADS) is promulgated, are you interested to join?

   ☐ Yes

   ☐ No

Section five: Release of survey information

1. Do you agree if AHWP TC WG2 publishes the information that you have provided in this survey?

   ☐ Yes

   ☐ No

Remark:

1. Thank you so much for your time and effort to complete this survey. Please note that the information collected in this survey will be used by AHWP TC WG2 as a reference for formulating the future activities for a harmonized post-market surveillance and vigilance systems. The survey result will also be published for the reference of regulatory authorities as well as traders.
2. Please return this questionnaire to the Chair and Co-chair of WG2 by sending emails to both **see_mda@dh.gov.hk** and **Miang.Tanakasemsub@bausch.com** or by fax to both **(852) 3157 1286** and **(852) 2213 3678 .**

END